

05-03-06 IFW
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: REILLY ET AL. Examiner: C. CROWDER
Serial No.: 10/697,995 Group Art Unit: 1644
Filed: OCTOBER 30, 2003 Docket: 11669.195USU1
Confirmation No.: 7395 Customer No.: 23552
Title: METHODS AND COMPOSITIONS FOR INCREASING ANTIBODY PRODUCTION

CERTIFICATE UNDER 37 CFR 1.10:

"Express Mail" mailing label number: EV 639593535 US
Date of Deposit: May 2, 2006

I hereby certify that this paper or fee is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450

By: Sheryl A. Boerboom
Name: Sheryl A. Boerboom

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

23552
PATENT TRADEMARK OFFICE

Sir:

We are transmitting herewith the attached:

- ☒ Transmittal Sheet in duplicate containing Certificate of Mailing
- ☒ Supplemental Information Disclosure Statement, Form 1449, 85 References
- ☒ Return postcard

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725. A duplicate of this sheet is enclosed.

Merchant & Gould P.C.
P.O. Box 2903
Minneapolis, MN 55402-0903
612.332.5300

By: Katherine M. Kowalchuk
Name: Katherine M. Kowalchuk
Reg. No.: 36,848
KKowalchuk:sab



10/697,995

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	REILLY ET AL.	Examiner:	C. CROWDER
Serial No.:	10/697,995	Group Art Unit:	1644
Filed:	OCTOBER 30, 2003	Docket No.:	11669.195USU1
Confirmation No.:	7395	Customer No.:	23552
Title:	METHODS AND COMPOSITIONS FOR INCREASING ANTIBODY PRODUCTION		

CERTIFICATE UNDER 37 CFR 1.10:

"Express Mail" mailing label number: EV 639593535 US
Date of Deposit: May 2, 2006

I hereby certify that this paper or fee is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

By: *Sheryl A. Boerboom*
Name: Sheryl A. Boerboom

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b))

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted before the mailing date of a first Office Action on-the-merits. Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

A copy of any foreign patent document or "Other Document" listed on the Form 1449 is enclosed, in accordance with 37 C.F.R. § 1.98(a)(2). Because this application was filed after June 30, 2003, copies of the U.S. Patents and U.S. patent publications listed on the enclosed Form 1449 are not provided.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to

establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

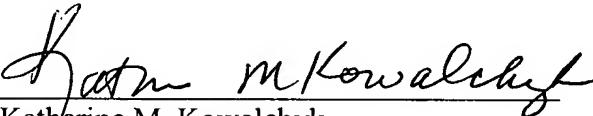
Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,


MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Date: _____

May 2, 2006


Katherine M. Kowalchyk
Reg. No. 36,848



FORM 1449*  INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 11669.195USU1	Application Number: 10/697,995
	Applicant: REILLY ET AL.	
	Filing Date: 10/30/2003	Group Art Unit: 1643

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,648,260	07/15/1997	Winter et al.			
	5,731,168	03/24/1998	Carter et al.			
	5,807,706	09/15/1998	Carter et al.			
	5,821,333	10/13/1998	Carter et al.			
	6,331,415 B1	12/18/2001	CABILLY ET AL.			
	2005/0048572 A1	03/03/2005	Reilly et al.			
	2005/0152894 A1	07/14/2005	Krummen et al.			

FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 89/01974	03/09/1989	PCT				
	WO 04/042017 A2	05/21/2004	PCT				
	WO 05/027966 A2	03/31/2005	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	Aruffo et al., "CD44 is the Principal Cell Surface Receptor for Hyaluronate" Cell 61:1303-1313 (Jun 29, 1990)
	Ashkenazi et al., "Immunoadhesins" Intern. Rev. Immunol. 10:219-227 (1993)
	Ashkenazi et al., "Protection Against Endotoxic Shock by a Tumor Necrosis Factor Receptor Immunoadhesin" Proc. Natl. Acad. Sci. 88:10535-10539 (Dec 1991)
	Atwell et al., "Stable heterodimers from remodeling the domain interface of a homodimer using a phage display library" J.Mol.Biol. 270(1):26-35 (1997)
	Bennett et al., "Extracellular Domain-IgG Fusion Proteins for Three Human Natriuretic Peptide Receptors. Hormone Pharmacology and Application to Solid Phase Screening of Synthetic Peptide Antisera" The Journal of Biological Chemistry 266(34):23060-23067 (1991)
	Berg et al., "Bispecific Antibodies that Mediate Killing of Cells Infected with Human Immunodeficiency Virus of Any Strain" Proc. Natl. Acad. Sci. USA 88:4723-4727 (June 1991)
	Brekke O H et al., "The structural requirements for complement activation by IgG: does it hinge on the hinge?" Immunol Today 16(2):85-90 (Feb 1995)
	Brennan et al., "Preparation of bispecific antibodies by chemical recombination of monoclonal immunoglobulin G _{sub1} nor fragments" Science 229:81-83 (July 5, 1985)

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 11669.195USU1	Application Number: 10/697,995
	Applicant: REILLY ET AL.	
	Filing Date: 10/30/2003	Group Art Unit: 1643

	Byrn et al., "Biological Properties of a CD4 Immunoaderhin" Nature 344:667-670 (April 12, 1990)
	Canevari et al., "Regression of advanced ovarian carcinoma by intraperitoneal treatment with autologous T lymphocytes retargeted by a bispecific monoclonal antibody" J Natl Cancer Inst. 87(19):1463-1469 (Oct 4, 1995)
	Capon et al., "Designing CD4 Immunoaderhins for AIDS Therapy" Nature 337:525-531 (Feb 9, 1989)
	Carpenter et al., "Non-Fc Receptor-Binding Humanized Anti-CD3 Antibodies Induce Apoptosis of Activated T Cells" J. Immunol. 165:6205-6213 (2000)
	Carter, "Bispecific human IgG by design" J Immunol Methods 248(1-2):7-15 (Feb 1, 2001)
	Chalupny et al., "T-cell activation molecule 4-1BB binds to extracellular matrix proteins" Proc. Natl. Acad. Sci. USA 89(21):10360-10364 (Nov 1992)
	Cunningham and Wells, "High-Resolution Epitope Mapping of hGH-Receptor Interactions by Alanine-Scanning Mutagenesis" Science 244:1081-1085 (Jun 2, 1989)
	Dietsch et al., "Bispecific Receptor Globulins, Novel Tools for the Study of Cellular Interactions" Journal of Immunological Methods 162:123-132 (1993)
	Duncan et al., "Localization of the Binding Site for the Human High-Affinity Fc Receptor on IgG." Nature 332:563-564 (Apr 7, 1988)
	Ellman et al., "Biosynthetic Method for Introducing Unnatural Amino Acids Site-Specifically into Proteins" Meth. Enzym. 202:301-336 (1991)
	Fanger et al., "Bispecific Antibodies" Critical Reviews in Immunology 12(3,4):101-124 (1992)
	Gascoigne et al., "Secretion of a chimeric T-cell receptor-immunoglobulin protein" Proc Natl Acad Sci U S A. 84(9):2936-2940 (May 1987)
	Gazzano-Santoro et al., "A Non-Radioactive Complement-Dependent Cytotoxicity Assay for Anti-CD20 Monoclonal Antibody" Journal of Immunological Methods. 202(2):163-171 (Mar 28, 1997)
	Gillies et al., "Antigen Binding and Biological Activities of Engineered Mutant Chimeric Antibodies with Human Tumor Specificities" Hum. Antibod. Hybridomas 1(1):47-54 (1990)
	Gruber et al., "Efficient Tumor Cell Lysis Mediated by a Bispecific Single Chain Antibody Expressed in Escherichia coli" Journal of Immunology 152:5368-5374 (1994)
	Hammerling et al., "Use of hybrid antibody with anti-147G and anti-ferritin specificities in locating cell surface antigens by electron microscopy" Journal of Experimental Medicine 128:1461-1469 (1968)
	Harris, "Production of humanized monoclonal antibodies for in vivo imaging and therapy" Biochemical Society Transactions 23:1035-1038 (1995)
	Hayden et al., "Antibody engineering" Curr Opin Immunol. 9(2):201-212 (Apr 1997)
	Hollinger et al., "Diabodies": Small Bivalent and Bispecific Antibody Fragments" Proc. Natl. Acad. Sci. USA 90:6444-6448 (Jul 1993)

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 11669.195USU1	Application Number: 10/697,995
	Applicant: REILLY ET AL.	
	Filing Date: 10/30/2003	Group Art Unit: 1643

	Hsieh-Ma et al., "In vitro cytotoxic targeting by human mononuclear cells and bispecific antibody 2B1, recognizing c-erbB-2 protooncogene product and Fc gamma receptor III" Cancer Research 52(24):6832-6839 (Dec 15, 1992)
	Hsu et al., "A Humanized Anti-CD3 Antibody, HuM291, With Low Mitogenic Activity, Mediates Complete And Reversible T-Cell Depletion in chimpanzees" Transplantation 68(4):545-554 (1999)
	Hurle and Gross, "Protein Engineering Techniques for Antibody Humanization" Curr. Op. Biotech. 5:428-433 (1994)
	Idusogie et al., "Mapping of the C1q Binding Site on Rituxan, A Chimeric Antibody with a Human IgG1 Fc" J. Immunol. 164(8):4178-4184 (2000)
	Jefferis et al., "Glycosylation of antibody molecules: structural and functional significance" Chem. Immunol. 65:111-128 (1997)
	Jefferis et al., "IgG-Fc-mediated effector functions: molecular definition of interaction sites for effector ligands and the role of glycosylation" Immunol Rev. 163:59-76 (1998)
	Jefferis et al., "Interaction sites on human IgG-Fc for Fc gamma R: current models" Immunol. Lett. 82(1-2):57-65 (2002)
	Karpovsky et al., "Production of target-specific effector cells using hetero-cross-linked aggregates containing anti-target cell and anti-Fc gamma receptor antibodies" J Exp Med. 160(6):1686-1701 (Dec 1, 1984)
	Klein et al., "Expression of biological effector functions by immunoglobulin G molecules lacking the hinge region" Proc. Natl. Acad. Sci. USA 78(1):524-528 (Jan 1981)
	Kon et al., "Randomised, dose-ranging, placebo-controlled study of chimeric Antibody to CD4 (keliximab) in Chronic Severe Asthma" Lancet 352:1109-1113 (1998)
	Kostelny et al., "Formation of a Bispecific Antibody by the Use of Leucine Zippers" Journal of Immunology 148(5):1547-1553 (Mar 1, 1992)
	Kroesen et al., "Local antitumour treatment in carcinoma patients with bispecific-monoclonal-antibody-redirected T cells" Cancer Immunol Immunother. 37(6):400-407 (Nov 1993)
	Kroesen et al., "Phase I study of intravenously applied bispecific antibody in renal cell cancer patients receiving subcutaneous interleukin 2" Br J Cancer 70(4):652-661 (Oct 1994)
	Kufer et al., "A revival of bispecific antibodies" Trends Biotechnol. 22(5):238-244 (May 2004)
	Kurschner et al., "Construction, purification, and characterization of new interferon γ (IFN γ) inhibitor proteins. Three IFN γ receptor-immunoglobulin hybrid molecules" Journal of Biological Chemistry 267(13):9354-9360 (1992)
	Le Doussal et al., "Bispecific Monoclonal Antibody-Mediated Targeting of an Indium-111-Labeled DTPA Dimer to Primary Colorectal Tumors: Pharmacokinetics, Biodistribution, Scintigraphy and Immune Response" J. Nucl. Med. 34:1662-1671 (1993)
	Le Doussal et al., "Bispecific-Antibody-Mediated Targeting of Radiolabeled Bivalent Haptens: Theoretical, Experimental and Clinical Results" Int. J. Cancer Suppl. 7:58-62 (1992)
	Lesslauer et al., "Recombinant Soluble Tumor Necrosis Factor Receptor Proteins Protect Mice From Lipopolysaccharide-induced Lethality" European Journal of Immunology 21:2883-2886 (1991)
	Linsley et al., "Binding of the B cell activation antigen B7 to CD28 costimulates T cell proliferation and interleukin 2 mRNA accumulation" J Exp Med. 173(3):721-730 (Mar 1, 1991)

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 11669.195USU1	Application Number: 10/697,995
	Applicant: REILLY ET AL.	
	Filing Date: 10/30/2003	Group Art Unit: 1643

	Linsley et al., "CTLA-4 is a second receptor for the B cell activation antigen B7" J Exp Med. 174(3):561-569 (Sep 1, 1991)
	Lisowska, "The role of glycosylation in protein antigenic properties" Cell. Mol. Life Sci. 59(3):445-455 (2002)
	Michaelson T E et al., "One disulfide bond in front of the second heavy chain constant region is necessary and sufficient for effector functions of human IgG3 without a genetic hinge" Proc Natl Acad Sci U S A. 91(20):9243-9247 (Sep 27, 1994)
	Milstein and Cuello, "Hybrid Hybridomas and Their Use in Immunohistochemistry" Nature 305:537-540 (Oct 6, 1983)
	Mimura et al., "The molecular specificity of IgG-Fc interactions with Fc gamma receptors" Adv. Exp. Med. Biol. 495:49-53 (2001)
	Muller et al., "The first constant domain (C(H)1 and C(L)) of an antibody used as heterodimerization domain for bispecific miniantibodies" FEBS Letters 422(2):259-264 (Jan 30, 1998)
	Nolan et al., "Bifunctional antibodies: concept, production and applications" Biochimica et Biophysica Acta 1040:1-11 (1990)
	Noren et al., "A general method for site-specific incorporation of unnatural amino acids into proteins" Science 244(4901):182-188 (Apr 14, 1989)
	Peipp & Valerius, "Bispecific antibodies targeting cancer cells" Biochem Soc Trans. 30(4):507-511 (Aug 2002)
	Peppel et al., "A Tumor Necrosis Factor (TNF) Receptor-IgG Heavy Chain Chimeric Protein as a Bivalent Antagonist of TNF Activity" Journal of Experimental Medicine 174:1483-1489 (Dec 1991)
	Perez et al., "Specific targeting of cytotoxic T cells by anti-T3 linked to anti-target cell antibody", Nature 316:354-256 (1985)
	Ponder and Richards, "Tertiary templates for proteins. Use of packing criteria in the enumeration of allowed sequences for different structural classes" J Mol Biol. 193(4):775-791 (Feb 20, 1987)
	Presta, "Engineering antibodies for therapy" Current Pharmaceutical Biotechnology 3(3):237-256 (2002)
	Radaev et al., "Recognition of immunoglobulins by Fc gamma receptors" Molecular Immunology 38(14):1073-1083 (2001)
	Ridgway and Gorman, "Expression and Activity of IgE Receptor Alpha Chain-IgG Chimeric Molecules" Journal of Cell Biology 115:250a (Abstract No. 1448) (1991)
	Rodrigues et al., "Engineering a humanized bispecific F(ab') ₂ fragment for improved binding to T cells" Int. J. Cancer (Suppl.) 7:45-50 (1992)
	Rudd et al., "Glycosylation and the Immune System" Science 291:2370-2376 (2001)
	Segal et al., "Introduction: Bispecific Antibodies" J Immunol Methods 248(1-2):1-6 (Feb 1, 2001)
	Segal et al., "Targeting and Activation of Cytotoxic Lymphocytes" Chem. Immunol. 47:179-213 (1989)
	Shalaby, et al., "Development of Humanized Bispecific Antibodies Reactive with Cytotoxic Lymphocytes and Tumor Cells Overexpressing the HER2 Protooncogene" Journal of Experimental Medicine 175:217-225 (Jan 1992)
	Songsivilai et al., "Bispecific antibody: a tool for diagnosis and treatment of disease" Clin. Exp. Immunol. 79:315-321 (1990)
	Stamenkovic et al., "The B Lymphocyte Adhesion Molecule CD22 Interacts with Leukocyte Common Antigen CD45RO on T Cells and \1412-6 Sialyltransferase, CD75, on B Cells" Cell 66:1133-1144 (Sep 20, 1991)

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 11669.195USU1	Application Number: 10/697,995
	Applicant: REILLY ET AL.	
	Filing Date: 10/30/2003	Group Art Unit: 1643

	Stickney et al., "Bifunctional Antibody: A Binary Radiopharmaceutical Delivery System for Imaging Colorectal Carcinoma" Cancer Research 51:6650-6655 (Dec 15, 1991)
	Talac & Nelson, "Current perspectives of bispecific antibody-based immunotherapy" J Biol Regul Homeost Agents 14(3):175-181 (Jul 2000)
	Trauneker et al., "Highly Efficient Neutralization of HIV with Recombinant CD4-immunoglobulin Molecules" Nature 339:68-70 (May 4, 1989)
	Valone et al., "Phase Ia/Ib trial of bispecific antibody MDX-210 in patients with advanced breast or ovarian cancer that overexpresses the proto-oncogene HER-2/neu" J Clin Oncol. 13(9):2281-2292 (Sep 1995)
	Van der Lubbe et al., "Chimeric CD4 monoclonal antibody cM-T412 as a therapeutic approach to rheumatoid arthritis" Arthritis and Rheumatism 36(10):1375-1379 (1993)
	van Spriel et al, "Immunotherapeutic perspective for bispecific antibodies" Immunol Today 21(8):391-397 (Aug 2000)
	Vaswani and Hamilton, "Humanized Antibodies as Potential Therapeutic Drugs" Ann. Allergy, Asthma & Immunol. 81:105-119 (Aug 1998)
	Watson et al., "A Homing Receptor-IgG Chimera as a Probe for Adhesive Ligands of Lymph Node High Endothelial Venules" Journal of Cell Biology 110:2221-2229 (1990)
	Watson et al., "Neutrophil Influx into an Inflammatory Site Inhibited by a Soluble Homing Receptor-IgG Chimaera" Nature 349:164-167 (Jan 10, 1991)
	Weiner et al., "A Human Tumor Xenograft Model of Therapy with a Bispecific Monoclonal Antibody Targeting c-erbB-2 and CD16" Cancer Research 53:94-100 (Jan 1, 1993)
	Weiner et al., "Phase I trial of 2B1, a bispecific monoclonal antibody targeting c-erbB-2 and Fc gamma RIII" Cancer Research 55(20):4586-4593 (Oct 15, 1995)
	Wright and Morrison, "Effect of Glycosylation on Antibody Function: Implications for Genetic Engineering" Trends in Biotechnology 15:26-32 (1997)
	Xu et al., "In vitro characterization of five humanized OKT3 effector function variant antibodies" Cellular Immunology 200(1):16-26 (2000)
	Zettlmeissl et al., "Expression and Characterization of Human CD4: Immunoglobulin Fusion Proteins" DNA and Cell Biology 9(5):347-353 (1990)

23552

PATENT TRADEMARK OFFICE

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	